Myths and Facts About Anthrax Vaccine

- MYTH: Anthrax vaccine is dangerous and can cause death. FACT: Anthrax vaccine is as safe as any other vaccine. Like any vaccine, death can occur after vaccination, but so few deaths can plausibly be associated to a specific vaccine or event that it is hard to evaluate the risk. For any vaccine, any death reported to the Vaccine Adverse Event Reporting System (VAERS) is thoroughly examined to ensure that it is not related to a new vaccine related problem. The Department of Defense, Food and Drug Administration, Centers for Disease Control and Prevention, and an independent panel of civilian physicians review reports of death or serious illness that might possibly be associated with anthrax vaccination. These groups all agree that anthrax vaccine is not associated with any unexpected patterns of adverse events. The National Academy of Sciences' Institute of Medicine reported in March 2002, "There is no evidence that life-threatening or permanently disabling immediate-onset adverse events occur at higher rates in individuals who have received AVA [U.S. anthrax vaccine] than in the general population." In rare cases, patients experience serious adverse effects; these are treated and followed appropriately. "

- MYTH: Anthrax vaccine causes terrible side effects. FACT: Based on over 30 years of anthrax vaccine use, we know that severe, albeit transient, injection site reactions do occur. It is known that from 30 to 60 percent of people who receive anthrax vaccine will develop an injection site reaction (less than one inch). About 1 in 100 develops a reaction five inches in diameter or larger. The rate of side effects away from the injection site is about the same as other vaccines: from 5 to 35 percent, with these events going away within a few days. The National Academy of Sciences' Institute of Medicine reported in March 2002, "Local events, especially redness, swelling, or nodules at the injection site, are associated with receipt of AVA [U.S. anthrax vaccine], are similar to the events observed following receipt of other vaccines currently in use by adults, and are fairly common" and "There is no evidence that life-threatening or permanently disabling immediate-onset adverse events occur at higher rates in individuals who have received AVA than in the general population."

- MYTH: Women have long-term side effects from anthrax vaccine more than men. FACT: Women experience more small injection site reactions than men. For skin reactions smaller than one inch in diameter, the likelihood is 60 percent for women and 30 percent for men. For side effects away from the injection site, the rates for men and women are about the same.

- MYTH: Antibiotics are more effective than anthrax vaccine. FACT: There is no better round-the-clock protection against anthrax infection than the anthrax vaccine. Antibiotics are effective when started immediately or very soon after exposure. However, not all exposures can be predicted in advance or even determined in very early stages, particularly in certain military situations. In such situations, the consequences for military personnel and their mission could be dire. This is not a risk DoD can afford to take. DoD will therefore vaccinate ahead of time for the best protection.

- MYTH: Anthrax vaccine only protects against cutaneous anthrax. FACT: While no vaccine is 100% effective, this vaccine will greatly reduce the risk of contracting anthrax regardless of route of exposure. Based on human and animal data, the National Academy of Sciences' Institute of Medicine concluded in March 2002 that anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of Bacillus anthracis."

- · MYTH: Anthrax vaccine won't protect against all strains of anthrax. FACT: Every disease-causing strain of Bacillus anthracis produces the same protein, a protein that is required to cause disease. The vaccine induces the production of antibodies that neutralize that protein. The National Academy of Sciences' Institute of Medicine concluded in March 2002 that "it is unlikely that either naturally-occurring or anthrax strains with bioengineered protective antigen could both evade AVA [the U.S. anthrax vaccine] and cause the toxicity associated with anthrax." "

- MYTH: Some lots of anthrax vaccine cause more problems than other lots. FACT: Based on self-administered surveys and spontaneous reports, lot-to-lot comparisons in the various human safety studies performed to date found no meaningful differences based on lot. No vial of anthrax vaccine was distributed by the manufacturer without lot-specific manufacturing and testing data, explicitly reviewed and approved by the Food and Drug Administration (FDA). The Department of Defense

uses only vaccine lots that the FDA released as meeting all applicable standards. ”

- MYTH: The anthrax vaccine is based on old technology. FACT: Anthrax vaccine was invented using mid-century technology that also led to highly successful vaccines against tetanus, diphtheria, and other infectious diseases. Today’s manufacturing of anthrax vaccine by BioPort meets all current Food and Drug Administration standards of production.

- MYTH: The Department of Defense added squalene, an oil naturally produced in the human body and by bacteria, to the vaccine in 1990-91 to stretch the supply. FACT: No one added squalene to anthrax vaccine. Food and Drug Administration (FDA) scientists found trace quantities of squalene in anthrax, diphtheria, and tetanus vaccines (less than the natural level of squalene in the human bloodstream). The FDA notes that these minute quantities could have come from the bacteria involved or from processing during FDA tests (squalene is present in the oil in fingerprints). The FDA called the squalene in vaccines "naturally occurring and safe."

- MYTH: The Food and Drug Administration revoked the license of BioPort, the Department of Defense’s vaccine supplier, because of manufacturing problems. FACT: BioPort’s predecessor, the Michigan Biological Products Institute (MBPI), owned by the State of Michigan, approved renovations in 1995 for the Lansing facility. In 1997, the Food and Drug Administration (FDA) issued a notice of intent to revoke licenses issued to MBPI. MBPI responded within 30 days with a strategic plan for compliance to FDA standards. The manufacturer voluntarily closed the anthrax vaccine production line in January 1998 for renovation. BioPort submitted a highly detailed set of quality control documents to FDA in fall 2001. FDA approved BioPort’s facilities and processes, as they relate to the manufacture of anthrax vaccine, on January 31, 2002.

- MYTH: The Centers for Disease Control and Prevention use of anthrax vaccine to Congressional staff and U.S. Postal Service workers was “experimental” and “investigational,” requiring informed consent, so the Department of Defense’s use of anthrax vaccine requires consent from servicemembers as well. FACT: The Department of Defense’s use of anthrax vaccine in the Anthrax Vaccine Immunization Program for pre-exposure prevention using six doses over eighteen months is consistent with the Food and Drug Administration-licensed use of the vaccine. The Centers for Disease Control and Prevention offer of anthrax vaccine for Congressional and U.S. Postal Service workers used anthrax vaccine for “post-exposure prophylaxis” in three doses. This is not a Food and Drug Administration-licensed use of the vaccine, therefore, in that case (post-exposure), the vaccine was administered under an “investigational new drug” protocol, with informed consent.

- MYTH: The anthrax vaccine can cause miscarriages. FACT: There is no study to support this claim. Consistent with the national standard and the Centers for Disease Control and Prevention recommendation, the Department of Defense policy does not vaccinate pregnant woman. Women who receive the vaccine get pregnant and deliver children at the same rates as unvaccinated women. A preliminary report (not yet published, not reviewed by peer scientists) suggested that women vaccinated during pregnancy might have an elevated rate of birth defects. However, medical scientists and study experts who have reviewed this preliminary information expressed concerns about the study’s methods, and recommended further analysis. The Department of Defense is working with the Centers for Disease Control and Prevention to see if these preliminary data are accurate, or if they are not.